

REMARKS

Claim 6 has been canceled without prejudice. Claim 1 has been amended. Support for the amendment to Claim 1 can be found throughout the specification and Claim 6 as originally filed. Claims 7-11 and 14-16 are withdrawn. Accordingly, Claims 1-5 and 12-13 are presented.

Rejection of Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e)

The Examiner rejected Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e) as allegedly anticipated by Lovett (U.S. Patent No. 6,881,419, hereinafter “Lovett”). Specifically, the Examiner asserts that Lovett describes a composition wherein the composition includes all of the limitations of the rejected claims. In order to expedite the allowance of the claims set forth in the instant application, Applicants have amended independent Claims 1-3 to include the limitations of Claim 6. The amended claims are clearly novel over the Lovett reference.

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (*Fed. Cir. 1985*). More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (*Fed. Cir. 1994*). “To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim.” *Brown v. 3M*, 265 F.3d 1349 (*Fed. Cir. 2001*). In addition, “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385 (*CCPA 1970*).

Lovett fails to describe all of the elements of independent Claims 1, 2 or 3 as amended, or any of the claims dependent thereon. Specifically, Lovett fails to disclose an oral composition or agent comprising a soy isoflavone aglycone in the genistein/daidzein weight ratio defined in amended Claim 1. Lovett relates to vitamin formulations for enhanced calcium absorption. The vitamin supplements of Lovett can include ingredients such as calcium, vitamin D₃ and soy isoflavonoids. In contrast, Claim 1 recites an oral composition for alveolar bone resorption inhibition and periodontal membrane loss inhibition, comprising a soy isoflavone aglycone, calcium and vitamin D₃, “wherein the soy isoflavone aglycone is obtained from or in an extract from whole-grain soy; the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1; and the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90%.” Lovett fails to disclose a composition comprising soy

isoflavone aglycone in the genistein/daidzein ratios and proportions as defined in Claims 1, 2 or 3 as amended.

For at least this reason, Lovett fails to disclose all of the elements recited in independent Claims 1, 2 and as amended. Since each of dependent Claims 4, 5, 12 and 13 depends directly on Claim 1 or 3, Applicants submit that those claims are also not anticipated by Lovett.

In view of the foregoing amendment and remarks, Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e).

Rejection of Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e) or § 103(a)

The Examiner rejected Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e) as allegedly anticipated by Lovett or in the alternative, under 35 U.S.C. § 103(a) as obvious over Lovett. Specifically, the Examiner asserts that Lovett describes a composition wherein the composition includes all of the limitations of the rejected claims. In the alternative, the Examiner asserts that the claimed invention was at least *prima facie* obvious in the absence of evidence to the contrary. In particular, the Examiner asserts it would be obvious to adjust particular conventional working conditions, and characterizes such adjustment as “merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.” However, as discussed below, this characterization of the differences between the claimed invention and the Lovett reference is inaccurate.

As discussed above, independent Claims 1, 2 and 3 as amended are not anticipated by Lovett, at least because of the genistein/daidzein ratios and the proportions of genistein/daidzein recited in these claims. In particular, the ratio of genistein/daidzein as defined in the amended claims is significantly different from that of the natural soy isoflavones used by Lovett. Moreover, the proportion of the total weight of genistein and daidzein in natural soy isoflavone aglycone is far less than that of the presently claimed soy isoflavone. In support of this, Applicants enclose herewith References 1 and 2:

1. Adrian A. Franke et al, Proceedings of the Society for Experimental Biology and Medicine, Vol. 217, 263-273 (1998).
2. Shigemitsu Kudou et al., Agricultural and Biological Chemistry, Vol. 46, No.1, pp.1-5 (1982).

These references show that the abundance ratio of daidzein is higher than genistein in natural soy beans as well as in hypocotyls of soy beans and that the proportion of aglycon in total isoflavones is very small (see Table III of reference 1 and Table IV of reference 2). The data of these references are organized in the following table:

	Aglcone			Glycoside or its derivatives		Total isoflavones (C)	(A+B)/C
	Daidzein (A)	Genistein (B)	A+B	Daidzin	Genistin		
Soybean	52	28	80	861	735	1789	0.04
Hypocotyl	1020	350	1370	7430	3670	21850	0.06

*The values are calculated in mg/kg.

As shown in the above table, the ratio of genistein/daidzein is 0.54:1 in natural soybean and 0.34:1 in hypocotyls; and the ratio of aglycon to total isoflavones is 4% in natural soybean and 6% in hypocotyls. This data shows that daidzein exists more than genistein in natural soy beans, and that there exists very little aglycon (genistein and daidzein) compared to total soy isoflavones in nature. In contrast, amended Claims 1, 2 and 3 recite that the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1; and that the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90%. Therefore, the composition of the soy bean extract of the present invention is very unique compared to that of natural soy bean.

Contrary to the assertion of the Examiner, the recited ratios and proportions cannot simply be obtained by judicious selection and routine optimization. In light of the dramatic differences from natural soy bean content, one skilled in the art would have absolutely no reason to arrive at the genistein/daidzein ratios recited in the present claims. It is only with improper hindsight and Applicant's disclosure as a blueprint that the particular ratios recited in Claims 1, 2, and 3 as amended would have been obvious. Even under the looser standard set forth in the recent *KSR* decision of the U.S. Supreme Court, this clearly does not support *prima facie* showing of obviousness.

In light of the foregoing, Applicants submit that Claims 1-6, 12 and 13 are not anticipated under 35 U.S.C. § 102(e) and are not obvious under 35 U.S.C. § 103(a). As such, Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration of the outstanding rejections and, particularly, that all claims be allowed. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully invited to call the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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